

## **EPA Decides Plan of Action for Four IRIS Assessments on Hold**

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**WASHINGTON** – The U.S. Environmental Protection Agency (EPA) announced today its decisions on how to move forward with the development of four draft IRIS (Integrated Risk Information System) assessments that were previously placed on hold - methanol, MTBE, ETBE and acrylonitrile. EPA was holding these assessments due to a report (referred to in EPA's press release) from the National Toxicology Program (NTP) within the National Institute of Environmental Health Sciences (NIEHS). The report outlined a recent review by NTP of a research study completed by the Ramazzini Institute (RI) that identified differences of opinion in the evaluation of certain pathology findings for methanol. The NTP report recommended that pathology reviews be carried out to further resolve the differences of opinion in the diagnoses of certain tumors reported in the methanol research study. As a result, EPA and NIEHS are jointly sponsoring an independent Pathology Working Group (PWG) review, in cooperation with the RI, of selected studies, including the methanol study. NIEHS is overseeing the PWG review which has been designed in accordance with standard procedures established for NTP pathology reviews and is being carried out over the course of the next several months. The results of the PWG review will be made publicly available.

EPA's decisions on the four draft IRIS assessments have been determined separately based on consideration of the specific relevance of RI data in the assessments. The NTP report specifically identified differences concerning the diagnoses of lymphomas and leukemias in the methanol study. As a result, in June 2010, EPA placed the external peer review of the IRIS Methanol Toxicological Review (January 2010 draft) on hold. The cancer assessment for methanol will remain on hold until the completion of the PWG review. However, the tumor diagnoses under review are not related to the non-cancer assessment of health effects that are included in the draft assessment. Therefore, the IRIS Methanol Toxicological Review (non-cancer) (March 2011 draft) has recently been released for external peer review. More information on the peer review of the non-cancer methanol assessment is available on the IRIS website.

Leukemias and lymphomas were also diagnosed in the RI studies of MTBE and ETBE. Tumors of other pathological types (solid tumors) were identified in RI studies of acrylonitrile, as well as MTBE and ETBE. It is anticipated that the results of the PWG review will inform the interpretation of the tumor findings for these three assessments. However, upon further examination of the available database for these chemicals, EPA has determined that reliance on RI results is not necessary in order to continue with assessment development, including an assessment of cancer risks.

In addition, the Agency will review the relevance of findings from the PWG review for the two final assessments posted on IRIS, 1,1-dichloroethylene and vinyl chloride. EPA continues to support the conclusions of these assessments.